

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT EXAMINING OPERATION**

Applicant(s): Glen H. ERIKSON et al.

Serial No: 09/911,047

Group Art Unit: 1634

Filed: July 23, 2001

Examiner: Betty J. Forman

Att. Docket No.: E1047/20060

Confirmation No.: 3230

For: HOMOGENEOUS ASSAY OF BIOPOLYMER BINDING BY MEANS OF
MULTIPLE MEASUREMENTS UNDER VARIED CONDITIONS

REQUEST FOR RECONSIDERATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Final Rejection dated November 4, 2005, the time for responding thereto being extended in accordance with a Petition for Extension of Time submitted concurrently herewith, favorable reconsideration is respectfully requested in view of the following remarks.

Claims 1-4, 6-9 and 12-37 are pending.

Rejections under 35 U.S.C. § 112

Claims 17-19, 27-29 and 33-37 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. This rejection is respectfully traversed.

a) **Claims 17-19**

In Paragraph 4 of the Final Rejection, the Examiner rejects Applicants' previous arguments because the passages of the 09/909,496 application cited in support are allegedly focused only on the meanings of the expressions "substantially free of Hoogsteen bonding" and

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“free of G-G quartets”. The following quotation is taken from column 5, lines 57-62 of U.S. Pat.

No. 6,656,692, which issued from the ‘496 application:

Complexes of the invention preferably do not rely on Hoogsteen bonding or G-G quartets for maintenance of the complex structure, although Hoogsteen bonding and/or G-G quartets may be present. That is, complexes of the invention are preferably substantially free of Hoogsteen bonding, and substantially free of G-G quartets.

A person of ordinary skill in the art would clearly appreciate from this disclosure that Applicants were entitled to claims limited to assay methods in which the complexes formed in the assay are “substantially free of Hoogsteen bonding and substantially free of G-G quartets.”

In fact, claim 1 of the ‘692 patent includes part of this limitation:

1. A method for assaying a target . . . wherein said heteropolymeric probe sequence is bonded to said heteropolyrmeric target sequence by Watson-Crick complementary base interaction or by homologous base interaction free of Hoogsteen bonding

Thus, the PTO has already found that the ‘496 application provides adequate written description support for the limitation of being free of Hoogsteen bonding.

b) “Direct Application of Stimulus” in Claims 27-29, 33 and 36-37

Application of the first/second stimulus “directly” to the sample finds support in the present specification at, e.g., page 16, lines 16-20, which read as follows:

Samples were placed into a 3 mm quartz cuvette and were subjected to 1 or 5 volts DC (V) electrification for 15 seconds. The amperometric assay consisted of the monitoring of current while the voltage was being applied to the solution.

A person of ordinary skill in the art would recognize that applicants were in possession of an embodiment comprising “directly” applying the stimulus to the sample, based on this example

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in which DC voltage (i.e., the stimulus) was applied to the solution (i.e., the sample) to electrify the sample. The

In Paragraph 4 of the Final Rejection, the Examiner asserts that this "is but one of a very large genus of electronic stimuli." However, the Examiner has not provided any evidence or reasoned analysis showing the existence of such a large genus or why a single species does not entitle Applicants to claim the genus. As noted in MPEP 2163.05:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A "representative number of species" means that the species which are adequately described are representative of the entire genus. . . See, e.g., *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326-27 (CCPA 1981) (disclosure of a single method of adheringly applying one layer to another was sufficient to support a generic claim to "adheringly applying" because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered).

Thus, the Examiner has failed to make a *prima facie* showing of a failure to comply with the written description requirement.

c) Time Period for Voltage Application in Claims 34 and 36

Contrary to the Examiner's assertion that the specification does not "teach a time period of less than 15 seconds," Example 4 comprised the application of voltage for 11 seconds. See page 23, lines 24-26. Example 1 comprised the application of voltage for 15 seconds. Applicants are clearly entitled to claim application of voltage for 15 seconds or less. See page 16, lines 16-18. A person skilled in the art would have understood that the precise lower limit of the range could be defined by routine experimentation using the application as a guide.

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The lower limit of the range is not necessary for the claims to comport with the written description requirement of Section 112.

Accordingly, reconsideration and withdrawal of the written description rejection are respectfully requested.

Rejection under 35 U.S.C. § 103

Claims 1-4, 6-9 and 12-37 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Cummins et al. (U.S. Patent No. 5,874,213) in view of Meade et al. (U.S. Patent No. 6,071,699) and Blackburn et al. (Clinical Chemistry, 1991, 37:1534-1539). This rejection is respectfully traversed.

As noted in the Final Rejection at page 5, “Cummins et al. do not teach the method without separation of complexes.”

In the prior Office Action, no attempt was made to show any motivation to modify the teachings of Cummins et al. with the teachings of Meade et al. to reach the claimed invention with a reasonable expectation of success. See MPEP 2143. In the Final Rejection, the Examiner makes an attempt to show reasonable motivation, but it is simply not possible to show a reasonable motivation to modify an electrophoresis reference, such as Cummins et al., in a manner that precludes electrophoresis. As noted in MPEP 2143.01:

If [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Cummins et al. cannot be modified to exclude a separation step as separation is the very

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essence of the reference. A person of ordinary skill in the art would not be reasonably motivated to modify an electrophoretic assay reference to eliminate electrophoresis.

Accordingly, reconsideration and withdrawal of the obviousness rejection are respectfully requested.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

By



David M. Tener
Registration No. 37,054
Customer No. 03000
(215) 567-2010
Attorneys for Applicants

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